

PATENT SPECIFICATION

(11) 1298189

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DRAWINGS ATTACHED

(21) Application No. 21311/71 (22) Filed 19 April 1971
(31) Convention Application Nos. 9934 and 9935
(32) Filed 9 Feb. 1970 in
(33) United States of America (US)
(45) Complete Specification published 29 Nov. 1972
(51) International Classification A61N 1/38
(52) Index at acceptance A5R 85D1 85D3



(54) ELECTROMEDICAL APPARATUS

SPECIFICATION NO 1298189

By a direction given under Section 17 (1) of the Patents Act 1949 this application proceeded in the name of MIECZYSLAW MIROWSKI, route 3, Velvet Valley Way, Owings Mills, Maryland 21117, United States of America, a citizen of Israel.

THE PATENT OFFICE

R 68612/1

15 During the past several decades, coronary heart disease has come to occupy the first position among the causes of death in the developed areas of the world. In the United States, for example, this disease is responsible for over one-half million deaths yearly. And of this 20 number, more than half occur suddenly, outside the hospital, and therefore before the patient is able to obtain the necessary medical assistance. Although the precise cause of sudden death in coronary heart disease has not 25 yet been entirely clarified, the available evidence permits the medical field to ascribe death in the majority of these cases to grave disturbances in cardiac electrical activity resulting in ventricular fibrillation.

30 Recent experience has clearly demonstrated that ventricular fibrillation and its frequent precursor, ventricular tachycardia, are reversible phenomena when prompt defibrillation of the heart is instituted. Under such circumstances, 35 cardiac function can frequently be restored to normal without the patient suffering from residual disability. Unfortunately, however, the state of the art makes defibrillation very much dependent upon a highly specialized medical 40 environment, thus limiting such treatment to elaborately equipped modern hospitals.

At the present, therefore, a great need exists for a defibrillator which could be carried by those who are prone to having one of the many 45 life threatening arrhythmias generally dis-

60 utus can be recognized - who have experienced myocardial infarction, even though they may be surviving in good health, run a substantial risk of dying suddenly, a risk several times greater than that associated with the general population. Further, if patients with myocardial infarction have a history of serious ventricular arrhythmias and/or of cardiac arrest, or if evidence of persistent myocardial irritability is present, it may be logically assumed that the risk of sudden death is increased substantially. Patients like those described above would greatly benefit if an automatic, standby or demand defibrillator were available.

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Also, such an automatic defibrillator would be an asset to those hospital patients who have suffered myocardial infarction and who have been discharged from the well-equipped coronary care unit. Under such circumstances, the defibrillator could be implanted temporarily for the remainder of the expected hospital stay; or the defibrillator could be permanently implanted for use both in the hospital and after discharge. And another recognizable class of patients particularly in need of an automatic defibrillator is the class composed of those who have not shown prior histories of myocardial infarction but who show severe symptoms of coronary heart disease, such as ventricular arrhythmias resistant to medical treatment or angina pectoris.

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(54) ELECTROMEDICAL APPARATUS

(71) We, MEDTRONIC INC., a corporation organized and existing under the laws of the State of Minnesota, United States of America, of 3055 Old Highway Eight, Minneapolis, Minnesota 55418, United States of America, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and 5 by the following statement:—

This invention concerns electromedical apparatus and particularly concerns apparatus for the treatment of coronary heart disease.

During the past several decades, coronary 15 heat disease has come to occupy the first position among the causes of death in the developed areas of the world. In the United States, for example, this disease is responsible for over one-half million deaths yearly. And of this 20 number, more than half occur suddenly, outside the hospital, and therefore before the patient is able to obtain the necessary medical assistance. Although the precise cause of sudden death in coronary heart disease has not 25 yet been entirely clarified, the available evidence permits the medical field to ascribe death in the majority of these cases to grave disturbances in cardiac electrical activity resulting in ventricular fibrillation.

30 Recent experience has clearly demonstrated that ventricular fibrillation and its frequent precursor, ventricular tachycardia, are reversible phenomena when prompt defibrillation of the heart is instituted. Under such circumstances, 35 cardiac function can frequently be restored to normal without the patient suffering from residual disability. Unfortunately, however, the state of the art makes defibrillation very much dependent upon a highly specialized medical 40 environment, thus limiting such treatment to elaborately equipped modern hospitals.

At the present, therefore, a great need exists 45 for a defibrillator which could be carried by those who are prone to having one of the many life threatening arrhythmias generally dis-

cussed above. Thus, in some patients having coronary heart disease, a fatal outcome from ventricular tachycardia or ventricular fibrillation could be avoided, even in the absence of immediate medical assistance. The first step, of course, is the detection of those prone to suffering from cardiac malfunctions leading to ventricular tachycardia or ventricular fibrillation. 50

While it is not possible to predict with unerring exactness which patient suffering from coronary heart disease will be the victim of sudden death, several high risk groups of patients can be recognized. For example, patients who have experienced myocardial infarction, even though they may be surviving in good health, run a substantial risk of dying suddenly, a risk several times greater than that associated with the general population. Further, if patients with myocardial infarction have a history of serious ventricular arrhythmias and/or of cardiac arrest, or if evidence of persistent myocardial irritability is present, it may be logically assumed that the risk of sudden death is increased substantially. Patients like those described above would greatly benefit if an automatic, standby or demand defibrillator were available. 55

Also, such an automatic defibrillator would be an asset to those hospital patients who have suffered myocardial infarction and who have been discharged from the well-equipped coronary care unit. Under such circumstances, the defibrillator could be implanted temporarily for the remainder of the expected hospital stay; or the defibrillator could be permanently implanted for use both in the hospital and after discharge. And another recognizable class of patients particularly in need of an automatic defibrillator is the class composed of those who have not shown prior histories of myocardial infarction but who show severe symptoms of coronary heart disease, such as ventricular arrhythmias resistant to medical treatment or angina pectoris. 60 65 70 75 80 85 90

From the brief discussion above, there should be little doubt that the possible applications for an automatic defibrillator are numerous. And, as previously noted, there is at present no known device which meets the need. It is toward filling this gap in medical instrumentation that the present invention is directed.

According to this invention therefore there is provided a cardiac defibrillator including storage means for storing electrical energy, at least one electrode for connecting the storage means to the heart of a patient, switching means operable to discharge the storage means through the electrode into the heart, sensing means for connection with the heart for continually sensing the heart function, and a discriminator associated with the sensing means and adapted for discriminating between normal heart function and cardiac fibrillation as sensed by the sensing means, said sensing means and discriminator being arranged to be responsive to sensed cardiac fibrillation for automatically operating said switching means to cause the energy stored in said storage means to be applied through said electrode directly to the heart in order to defibrillate the malfunctioning heart.

The present invention relates to what is known in the art as a standby defibrillator, i.e. an electronic system which, after detecting one of the above-noted life threatening arrhythmias, automatically defibrillates the heart of the user. The defibrillator of the present invention may be installed in patients particularly prone to develop ventricular tachycardia and/or ventricular fibrillation, either on a temporary or a permanent basis. And, because it can be constructed of small size, the defibrillator of the present invention may be entirely implanted under the skin of the patient, or alternatively, may be carried externally, save for the sensing electrode and one shock-applying electrode.

Hereinafter described is an exemplary embodiment of this invention adapted for reliably sensing the differences between a properly functioning heart and one which has suddenly developed ventricular fibrillation, and which then delivers a defibrillating shock to the heart in fibrillation. The device is adapted to continue delivering intermittent shocks to the heart in the event that the heart fails to return to its normal behavior pattern, and has the ability of automatically regaining sensing control over a functional heart thereby ensuring that further shocks are inhibited after successful defibrillation has taken place.

The standby defibrillator hereinafter described has as its basic element, a capacitor capable of storing electrical energy in an amount sufficient to depolarize the human heart (of the order of 50 joules). Upon discharge of this capacitor a shock is delivered to the heart through two stimulating elec-

trodes. One of these electrodes is positioned within the right ventricle, thereby forming the distal tip of an intracardiac catheter. This electrode is introduced through a peripheral vein. The second stimulating electrode is positioned either on the surface of the chest, or is sutured under the skin of the anterior chest wall or directly to the ventricular myocardium.

The capacitor is associated with a sensing circuit connected to the proximal end of the intracardiac catheter and is adapted to respond to a signal recorded at the distal end of the catheter. The signal sensed by the catheter must, of course, be inherently related to some distinctive characteristic of ventricular tachycardia or ventricular fibrillation; and in a specific embodiment of the present invention, the pressure in the right ventricle is sensed. When this pressure falls below a given value on the order of 10 to 15 mm hg, the heart is malfunctioning and, therefore, the capacitor is discharged into the heart.

Between the sensing circuit and the capacitor, means are provided for delaying the repetition of depolarizing discharges for a preset period of time (of the order of 20 to 30 seconds). This delay is essential to give the heart the opportunity to convert spontaneously to a normal cardiac rhythm, and also to ensure that the abnormal heart conditions are, in fact, critical. Only in the absence of a successful conversion is a subsequent shock delivered to the heart. In a particular embodiment of the present invention, the time delay is brought about with the aid of a sawtooth generator, a relay and the charge time of the storage capacitor.

In the accompanying drawings:

Figure 1 is a side view of a combination sensing probe and shock-applying probe forming a part of the embodiment hereinafter described;

Figure 2 illustrates a typical pressure curve for the right ventricle of a normally functioning heart;

Figure 3 is a circuit schematic of the electronics of the exemplary standby defibrillator hereinafter described; and

Figure 4 is a graph of voltage versus time illustrating the operation of the sawtooth generator forming a part of the described embodiment.

With reference first to Figure 1, the sensing and shock delivering probes will be described. The sensing probe is shown generally at 10 and comprises a main body portion 12 and a pressure sensitive bulb 14. Electrical connections to the bulb 14 are made at junction box 16. One of the shock delivering probes is shown generally at 18 and comprises a main body portion 20, a first ring electrode 22 and a second ring electrode 24. As will be explained below, the electrodes 22 and 24 are short-circuited together during the operation of the device, forming a composite electrode shown at 26. The main body 12 of the sensing

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probe 10 is in the shape of a flat ribbon, and the body of the bulb 14 is spherical. The shock delivering probe 18 is substantially cylindrical.

As noted previously, the combination sensing probe 10 and shock delivering probe 18 is, during operation, positioned in the right ventricle of the heart. These probes are introduced into the heart through a peripheral vein by means of surgery very similar to that involved in the implantation of a pacemaker probe.

The shock delivering electrodes are two in number. The first electrode is the composite electrode 26 and is carried by the shock delivering probe 18. The second electrode is shown at 28 and, in the preferred embodiment of this invention, is a flat plate either placed on the surface of the chest, sutured under the skin of the anterior chest wall or applied directly to the ventricular myocardium.

When the sensing probe 10 and the shock delivering probe 18 are inserted into the heart, the electrodes 22 and 24 are independent of one another. At this time, conventional pacemaking signals are applied between the electrodes 22 and 24. Since the heart responds favorably to the pacemaking signals only if the probe 18 is properly positioned, this method is suitable for checking the position of the probes 10 and 18. The probe location may, of course, be recognized by other methods such as, for example, fluoroscopy or pressure recordings. Once it is determined that the probes 10 and 18 are properly located, they are secured in place and the pacemaking electronics are disconnected. Then, the electrodes 22 and 24 are externally short-circuited together, and the electronic circuit associated with the standby defibrillator of the present invention is then connected to the probes 10 and 18 and the electrode 28. If a pacemaking function is also to be carried out, the pacemaker electronics will remain connected and the step of shorting together the electrodes 22 and 24 will be eliminated.

With reference now to Figure 2, there is illustrated a right ventricular pressure curve for a normally functioning heart. Pulses 30 and 32 are illustrated but, as is well known, these pulses repeat at the rate of approximately 60 to 70 per minute in a normally functioning heart. Figure 2 clearly shows that each pulse has a peak and that these peaks rise above a preset pressure indicated by the dotted line 38. This dotted line corresponds to the threshold between a healthy heart and one which is in need of defibrillation. When the height of the peaks 34 and 36 fall below the pressure indicated by line 38, the malfunction is sensed by probe 10 which, as will be described immediately below, initiates the defibrillation of the heart.

With reference then to Figure 3, the electronics associated with the standby defibrillator will be described. The electronics circuitry

of Figure 3 may conveniently be broken down into several component parts. The first part is a pressure transducer shown at 40, this pressure transducer being directly associated with the pressure sensing probe 10 shown in Figure 1. The next stage of the electronics is a combination of an amplifier and a sawtooth generator shown at block, 42. The amplifier is adapted to amplify the signals received from the pressure transducer 40. The sawtooth generator comprises a transistor and a capacitor connected between the collector of the transistor and ground. The signal from the sawtooth generator is then passed to an output amplifier shown at 44, which amplifier 44 in turn feeds its output signal to the base of a transistor associated with the relay stage shown at 46. The relay 46 is normally in its open state condition but, when it is closed, a DC signal is impressed upon a DC/DC converter stage 48. The DC/DC converter 48 boosts the input voltage from approximately 15 volts to an output voltage of approximately 2,500 volts. The 2,500 volt DC signal from the converter 48 is then fed to a storage capacitor 70 which is associated with a firing circuit the entire combination shown at 50. When the firing circuit 50 allows the capacitor 70 to discharge, the 2,500 volt signal is applied to the electrodes 26 and 28 illustrated in Figure 1. Therefore, when the pressure sensing probe 10 recognizes a malfunction in the heart, the capacitor, after a predetermined time delay, shocks the heart with approximately 2,500 volts at an energy level of approximately 50 joules which is sufficient to cause most hearts to defibrillate.

Still referring to Figure 3, but in greater detail, the circuitry associated with the present invention functions as follows. The pressure transducer 40 takes the form of a resistive bridge, one resistor of which is defined by the pressure sensor 14 on the tip of the probe 10. The remaining legs in the bridge are defined by resistors housed in the junction box 16 shown in Figure 1. The pressure transducer 40 is arranged so that the pressure sensed by element 14 is converted to an electrical signal, the amplitude of which is directly proportional to the pressure sensed by the element 14.

The output from the pressure transducer 40 is fed to a conventional multistage amplifier shown in block 42 which amplifies the received pulses and which then feeds these amplified pulses to the sawtooth generator in block 42. The trimming potentiometer 52 serves to balance the inputs to the amplifier.

With reference now to Figures 2 through 4, the operation of the sawtooth generator will be described. The sawtooth generator, if unaffected by the external environment, will have an output curve such as that shown at 54 in Figure 4. However, if a signal is fed to the sawtooth generator and if the signal is at least of a predetermined amplitude, then the output

voltage of the generator on lead 56 will immediately drop to zero and then again begin to climb. Therefore, if the sawtooth generator receives repetitious pulses of at least the predetermined voltage, then its output will be similar to that shown in Figure 4 at 58.

If the heart functions sensed by the pressure transducer 40 are normal, following the curve shown in Figure 2, then the amplified signal corresponding to a pulse in the right ventricular pressure will cause the output of the sawtooth generator to drop to zero. The threshold signal reaching the generator can be adjusted by adjusting the amplification factor of the signal amplifier shown in block 42. Amplifier 44 has a threshold which is adjusted by potentiometer 62 so that the amplifier 44 activates the relay 64 only after approximately six seconds of heart malfunction. If, then, the ventricular pressure falls lower than that value indicated by the dotted line 38, and so remains for the preset time interval, the amplified voltage reaching the generator 44, via lead 56, will be insufficient to cause the generator output to drop to zero. Rather, the generator output will follow the curve shown at 54 in Figure 4 and the threshold of amplifier 44 will be reached. Trimming potentiometer 60 is provided to balance the inputs provided to the output amplifier 44 from the lead 56 and potentiometer 62.

The output from the amplifier 44 is fed to the relay circuit 46. The relay contacts shown generally at 64 are initially set in the open-circuit condition, thereby isolating the 15 volt source from the DC/DC converter 48. Further, the relay 46 is set to close only after the current passing through coil 66 reaches a predetermined value. With reference to Figure 4, the voltage output of the sawtooth generator must be at the level 68, the threshold of amplifier 44 before the current in the coil 66 is sufficient to switch the relay 64 into its closed-circuit state.

When the relay 64 closes, then the 15 volt source is connected directly to the DC/DC converter 48. From Figures 2 through 4, it should be evident that approximately six seconds must elapse, with the heart continuously malfunctioning, before the relay 64 switches from its open-circuit mode to its closed-circuit mode. This will be apparent when one realizes that each "tooth" of the curve 58 corresponds to one peak of the right ventricular pressure curve and, as noted above, the peaks of the pressure curve repeat at approximately 60 to 70 per minute. Therefore, the heart pressure must be below the threshold level for approximately six seconds before input voltage is fed to the DC/DC converter 48. If the heart returns to its normal function at any time during that six seconds, then the sawtooth generator output response would drop to zero and the six second cycle would begin again.

With the relay 64 closed and a 15 volt DC

signal being impressed upon the converter 48, an output of 2,500 volts appears at the output terminals of the converter 48. This voltage is fed directly to storage capacitor 70. Simultaneously, the 2,500 volt signal is fed to a resistive chain and finally to the base of transistor 72 via a neon tube 74. A silicon controlled rectifier (SCR) is triggered on when transistor 72 becomes conductive.

The operation of the firing circuit 50 is as follows: the 2,500 volt signal from the converter 48 is fed to the capacitor 70. When the capacitor 70 is fully charged, the transistor 72 becomes conductive, due to the now-conducting neon tube 74. The resistor chains and the tube 74 are interconnected in such a manner that when the voltage across the capacitor 70 reaches the full 2,500 volts, then the tube 74 becomes conductive. When the tube 74 conducts, so too does transistor 72 and, therefore, SCR 76. Then, the full 2,500 volts pass through electrodes 26 and 28 thus shocking the heart with a voltage sufficient to cause defibrillation.

As above noted, it is important that a time period elapse between the detection of a heart malfunction and the delivery of the defibrillating shock to the heart. As also noted above, approximately six seconds of delay occur between the first detection of a malfunction and the closing of the relay 64. There is an additional delay, on the order of fifteen seconds, which is brought about by the charge time of the capacitor 70. That is, when the relay 64 closes, six seconds after the initial malfunction, the capacitor first begins to charge. The capacitor employed in the preferred embodiment charges in approximately fifteen seconds. Therefore, approximately twenty-one seconds elapse between the initial sensing of heart malfunction and the discharge of the capacitor into the heart. Naturally by varying the rise time of the sawtooth generator and the charge time of the capacitor, the delay period may be enlarged or contracted as desired. And, as mentioned above, if at any time during the delay period the heart returns to normal, then the delay period automatically begins again.

Above, a specific embodiment of the present invention has been described. It should be understood, however, that this description is given for illustrative purposes only and that many alterations and modifications may be practiced without departing from the scope of the invention. Just as a few examples, it should be understood that while in the specific embodiment of the present invention, the pressure in the right ventricle is sensed as an indication of heart malfunction, other sensing arrangements may be practiced. Further, a single SCR is used as a triggering device. It is possible to substitute this device for a plurality of SCR units or, alternatively, with a vacuum relay. Still further, while the above description shows a single

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storage capacitor, a series of capacitors could be employed. It is, therefore, the intent that the present invention not be limited to the above but be limited only as defined in the appended claims. 5

There has thus been described a cardiac defibrillator having the following advantages:

1. The defibrillator lies dormant during normal heart activity but automatically applies a shock to the heart when the heart functions become abnormal; more particularly, the defibrillator reliably senses the difference between a normally functioning heart and one that has suddenly developed abnormal function, and then automatically delivers a defibrillating shock to the heart. 10
2. The defibrillator is capable of delivering multiple shocks in the event that the heart is not successfully defibrillated by the initial shock. 20
3. The defibrillator automatically regains sensing control over a functioning heart, thereby inhibiting further shocks after successful defibrillation. 25
4. The defibrillator employs a heart-implanted catheter which may serve both for defibrillation and for pacing the heart if required. 30
5. The defibrillator can be made extremely compact so as to be totally implantable in the body of a patient.

WHAT WE CLAIM IS:—

1. A cardiac defibrillator including storage means for storing electrical energy, at least one electrode for connecting the storage means to the heart of a patient, switching means operable to discharge the storage means through the electrode into the heart, sensing means for connection with the heart for continually sensing the heart function, and a discriminator associated with the sensing means and adapted for discriminating between normal heart function and cardiac fibrillation as sensed by the sensing means, said sensing means and discriminator being arranged to be responsive to sensed cardiac fibrillation for automatically operating said switching means to cause the energy stored in said storage means to be applied through said electrode directly to the heart in order to defibrillate the malfunctioning heart. 40
2. A defibrillator as claimed in claim 1 including means for ensuring that a predetermined time delay exists between the initial sensing of a heart malfunction and the discharge of said storage means into the heart. 55
3. A defibrillator as claimed in claim 1 or 2, wherein said sensing means is adapted to be positioned within the heart for sensing the heart function during use of the defibrillator. 60
4. A defibrillator as claimed in any of the preceding claims wherein two said electrodes are provided and one of the two electrodes is adapted to be positioned within the heart during use of the defibrillator. 65
5. A defibrillator as claimed in any of the preceding claims wherein the storage means is a capacitor arranged to be charged in response to sensed cardiac fibrillation, and the arrangement is such that the charging of said capacitor is inhibited under conditions of normal heart activity. 70
6. A defibrillator as claimed in any of the preceding claims arranged so that a further defibrillatory impulse will be applied to the heart if the heart should fail to defibrillate after application of the first impulse. 75
7. A defibrillator as claimed in any of the preceding claims further including a cardiac pacemaker so associated with said electrode that said electrode functions in a pacemaking mode when not functioning in a defibrillating mode. 80
8. A defibrillator as claimed in any of the preceding claims wherein the sensing means includes a pressure responsive probe adapted to be inserted into the right cardiac ventricle to sense the pressure therein and issue an electrical signal whose amplitude is directly proportional to the said pressure. 85
9. A defibrillator as claimed in any of the preceding claims wherein said sensing means is adapted to provide an electrical signal the amplitude of which varies in dependence upon whether the heart function is normal or is abnormal and said discriminator is adapted to respond to said electrical signal by issuing an electrical signal of a first amplitude when the heart function is normal and by issuing an electrical signal of a second amplitude when the heart function is abnormal, the discharge of said storage means being arranged to be initiated by the signal of said second amplitude. 90
10. A defibrillator as claimed in claim 9 wherein means are provided for ensuring that a predetermined time delay exists between the initial sensing of a heart malfunction and the discharge of said storage means into the heart, the defibrillator furthermore being arranged so that the discharge of said storage means into the heart is inhibited in response to a signal of said first amplitude occurring during said time delay. 105
11. A defibrillator as claimed in claim 9 or 10 wherein said discriminator includes a sawtooth waveform generator adapted to provide a small amplitude output in response to normal heart function and a large amplitude output in response to abnormal heart function, the arrangement being such that the large amplitude output is produced only after a preset period of time has elapsed since abnormal heart function was sensed. 115
12. A defibrillator as claimed in claim 11 wherein an electromagnetic relay is connected to said sawtooth waveform generator and has normally open contacts adapted to be closed only when subjected to said large amplitude output from said discriminator. 120
13. A defibrillator as claimed in claim 12 130

wherein said contacts are arranged for coupling a low voltage supply to a voltage converter for deriving a voltage sufficient to defibrillate the heart, said voltage converter being operatively connected to said low voltage supply only when said contacts are closed. 5

14. A defibrillator as claimed in claim 13 wherein a storage capacitor constituting said storage means is connected directly to the output of said voltage converter. 10

15. A defibrillator as claimed in claim 14 wherein said switching means has a normally open-circuit state and is connected to said storage capacitor for switching to a closed-circuit state after said capacitor has fully charged, the closed-circuit state of said switching means resulting in the discharge of said storage capacitor into the heart. 15

16. A defibrillator as claimed in claim 15 including a trigger element responsive to the voltage across said capacitor to operate said switching means. 20

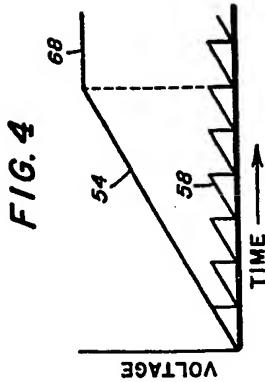
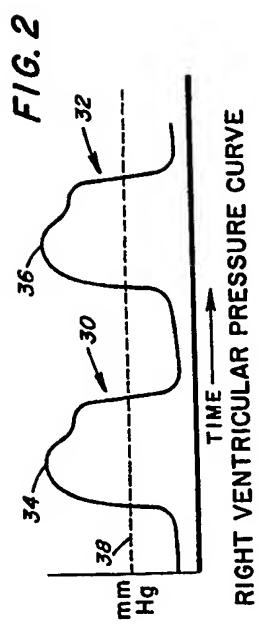
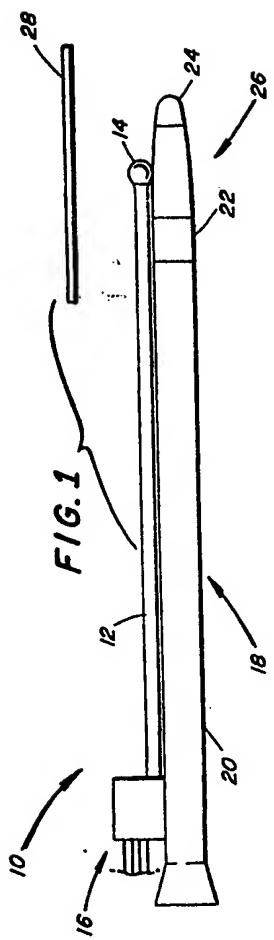
17. A defibrillator as claimed in any of the preceding claims wherein said switching means includes at least one controlled rectifier device. 25

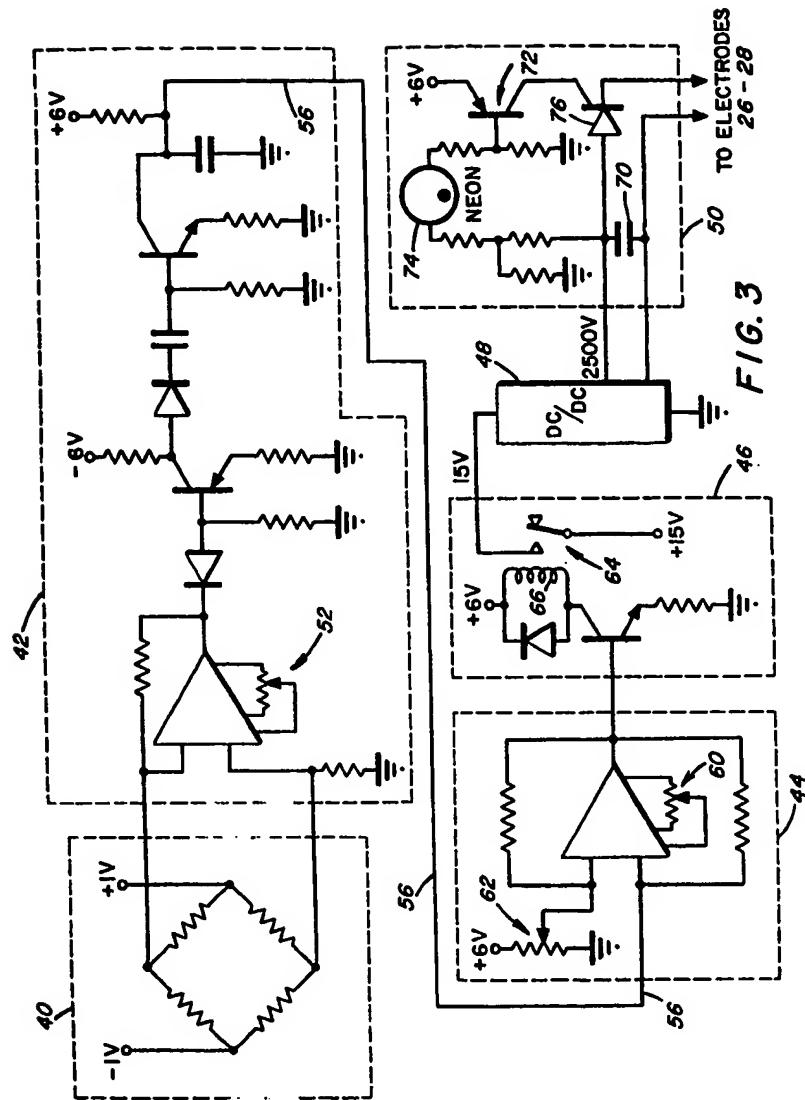
18. A cardiac defibrillator substantially as herein described with reference to the accompanying drawings.

19. An electronic device for automatically defibrillating a malfunctioning heart, the device comprising: an electronic probe for continually sensing the function of a heart and for issuing an electrical signal, the amplitude of which is proportional to the heart function; a discriminator associated with said probe for responding to the electrical signal issued thereby and for issuing an electrical signal of a first amplitude when the heart function is normal and for issuing an electrical signal of a second amplitude when the heart function is abnormal; means for storing electrical energy; at least one electrode associated with said storage means for connecting the storage means directly to the heart; and means for automatically switching said storage means into a discharge state, in response to a signal of said second amplitude, whereby the stored energy is applied directly to the heart through said electrode to defibrillate a malfunctioning heart. 30 35 40 45

For the Applicants,
FRANK B. DEHN & CO.,
Chartered Patent Agents,
Imperial House,
15-19, Kingsway,
London, W.C.2.

Printed for Her Majesty's Stationery Office by the Courier Press, Leamington Spa, 1972.
Published by the Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from
which copies may be obtained.





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